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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,751	12/06/2004	Mariko Miyashita	43888-346	5277
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EXAMINER				
DAM, DUSTIN Q				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/516,751

Applicant(s)

MIYASHITA ET AL.

Examiner

DUSTIN Q. DAM

Art Unit

1795

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)
Paper No(s)/Mail Date 12/6/2004
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Summary

1. This is the initial Office Action based on the Measuring Instrument for Biosensor and Measuring Method Using Same filed on February 18, 2004.
2. Claims 1-4 are currently pending and have been fully considered.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHMIDT (U.S. PG-Pub 2002/0144905 A1) in view of BLUM (U.S. Patent 4,264,327).
 - a. With regards to claim 1, SCHMIDT discloses a measuring device for a biosensor comprising, a supporting section for supporting, in a freely detachable manner, a

biosensor ([0044] discloses a supporting section "substrate" that can be constructed to support the sensor "material actually relevant" via "fastened or "constructed into" which is interpreted as freely detachable) biosensor comprising an electrode system having a measurement electrode (36a, FIG. 1) and a counter electrode (36b, FIG. 1), and a sample supply pathway (40, FIG. 1) having a portion that can be irradiated with light from the outside (38, FIG. 1 & see 1st sentence, [0086] "directing excitation light from the light source to the sample"), a plurality of connecting terminals electrically connected to said electrode system (ends of electrodes 36a & 36b, FIG. 1 inherently comprise a terminal on each end to connect to a "mechanism" {1st sentence, [0151]} in order to function), an electric signal measuring circuit (1st sentence, [0151] "mechanism adapted to apply and/or measure an electric potential") structurally capable of applying a voltage to said electrode system via connecting terminals and structurally capable of measuring variations in electric signal of said electrode system via said connecting terminals, a light source provided in such a position as to be able to irradiate said portion with light (1st sentence, [0086] "directing excitation light from the light source to the sample"), and a light receiving section and an optical signal measuring circuit (1st sentence, [0086] "optical relay structure" "detector"), said device being capable of measuring a volume ratio between a solid and a liquid contained in a sample by irradiation of said sample supply pathway with light (3rd – 6th sentence, [0083]).

SCHMIDT does not appear to explicitly disclose a measuring device for a biosensor comprising a calculating section for performing a calculation of said variations

in electric signal and said optical variations, and a display section for displaying results of said calculations.

However, BLUM discloses a measuring device for a biosensor comprising a processor and computer for performing calculations (line 23-26, column 10 discloses a computer structurally capable of calculating variations, hence concentration, and inherently comprising a display section). As recognized in the art and made evident by BLUM, the application of a computer for calculating and displaying data (such as concentration which is based on measurement variations) is a conventional technique.

Thus, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the measuring device for a biosensor, as disclosed by SCHMIDT, to include a computer for calculation and display of data, as disclosed by BLUM, because it is a known and conventional technique to include a computer with a biosensor in which one with ordinary skill would have predicted success in the combination. The combination of SCHMIDT and BLUM comprises a biosensor and computer in which the computer is structurally capable of performing a calculation of variations in electrical and optical signals and displaying the calculations.

b. With regards to claim 2, independent claim 1 is obvious over SCHMIDT in view of BLUM under 35 U.S.C. 103(a) as discussed above. The combination of SCHMIDT and BLUM discloses a measuring device for a biosensor comprising optical detection means in which the device is capable of measuring a volume ratio between a solid and a liquid contained in a sample by irradiation of said sample supply pathway with light (3rd – 6th sentence, [0083]). The combination of SCHMIDT and BLUM discloses a measuring

device for a biosensor structurally capable of measuring a volume ratio, which is a hematocrit value, between a solid and a liquid contained in a sample, which is blood, by irradiation of said sample supply pathway with light (3rd – 6th sentence, [0083]).

6. Claims 3 and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over SCHMIDT (U.S. PG-Pub 2002/0144905 A1) in view of OHARA et al. (U.S. PG-Pub 2002/0125145 A1).

a. With regards to claim 3, SCHMIDT discloses a measuring method of a specific substance comprising the steps of fixing a biosensor ([0044] discloses fixing “fastened” a biosensor “material actually relevant” to a substrate) which comprises an electrode system having a measurement electrode (36a, FIG. 1) and a counter electrode (36b, FIG. 1), and a sample supply pathway (40, FIG. 1) having a portion that can be irradiated with light from the outside (38, FIG. 1 & see 1st sentence, [0086] “directing excitation light from the light source to the sample”), connecting said electrode system of said biosensor to connecting terminals for measurement (ends of electrodes 36a & 36b, FIG. 1 inherently comprises connecting a terminal on each end to connect to a “mechanism” {1st sentence, [0151]} for measurement), supplying said biosensor with a sample (42, FIG. 1), turning on a light source to irradiate said portion with light ([0086] discloses “light source” and “directing excitation light from light source to sample” which inherently comprises turning on the light source), measuring optical variations in said portion via a light receiving section ([0086] discloses “detector”), performing a calculation of the measurement result in said measuring optical variations step ([0086] discloses “detector” and (3rd – 6th sentence, [0083] disclose light detector can be “used to infer properties”

which includes a volume ratio between a solid and a liquid in a sample “presence, size, shape, mobility, quantity, activity, and/or association state of selected components of the sample” which properties inherently comprises a calculation step from raw detected signals), applying a voltage to said electrode system via said connecting terminals after the lapse of the prescribed time (1st sentence, [0151] “applying” “electric potential across the aperture” which the sample is disposed, the lapse of prescribed time can be the time between no sample present and application of the sample between the aperture), measuring a current flowing in said electrode via said connecting terminals (1st sentence, [0151] “measure an electric potential”) performing a calculation of the measurement result in said measuring a current step (7th sentence, [0037] discloses “measuring changes in electrical properties across the aperture” which inherently comprises a calculation to acquire a change), and measuring a volume ratio between a solid and a liquid in said sample from the measurement result in said measuring optical variations step ([0086] discloses “detector” and (3rd – 6th sentence, [0083] disclose light detector can be “used to infer properties” which includes a volume ratio between a solid and a liquid in a sample “presence, size, shape, mobility, quantity, activity, **and/or** association state of selected components of the sample” the size and quantity of a solid component, and lack of presence in an area of the aperture).

SCHMIDT does not appear to explicitly disclose a measuring method of a specific substance wherein the step of measuring a volume ratio between a solid and a liquid in said sample is done to correct the electrical calculation result. However, SCHMIDT suggests analyzing samples such as biological cells from animals (1st

sentence, [0096]). It would have been obvious at the time of the invention to a person having ordinary skill in the art to analyze red blood cells in blood in the measuring method of a specific substance, as disclosed by SCHMIDT, because red blood cells in blood are one of a finite number of biological animal cells which are conventionally analyzed in the art and one of ordinary skill in the art would have good reason to pursue the known options within his or her technical grasp. The volume ratio between a solid and a liquid in the case of a red blood cell sample is commonly referred to as a hematocrit value.

OHARA et al. discloses a measuring method of a specific substance and discloses when measuring blood or a derivative thereof, the hematocrit value of the sample can be a source of analytical error (1st sentence, [0004]). OHARA et al. discloses correcting an electrochemically analyzed sample calculation based on a hematocrit calculation (5th sentence, [0009] & see [0015]).

Thus, at the time of the invention, it would have been obvious to a person having ordinary skill in the art to modify the measuring method of a specific substance, as disclosed by SCHMIDT, to perform the step of measuring a volume ratio between a solid and a liquid in the sample to correct an electrochemical calculation, as disclosed by OHARA et al., because a hematocrit value can be a source of analytical error and OHARA et al. suggest correcting an electrochemical calculation to obviate this error.

b. With regards to claim 4, independent claim 3 is obvious over SCHMIDT in view of OHARA et al. under 35 U.S.C. 103(a) as discussed above. The combination of SCHMIDT and OHARA et al. discloses a measuring method of a specific substance

wherein an optical calculation of a hematocrit value is preformed to correct an electrochemical measurement of the sample. SCHMIDT discloses a measurement method of a specific substance further comprising detecting the presence of said sample in said sample supply pathway from the measurement result in said step of calculating optical variations (3rd – 6th sentence, [0083] disclose light detector can be “used to infer properties” “presence”).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DUSTIN Q. DAM whose telephone number is (571)270-5120. The examiner can normally be reached on Monday through Thursday, 7:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Nam Nguyen can be reached on (571)272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Art Unit: 1795

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April 23, 2008

/PATRICK RYAN/

Supervisory Patent Examiner, Art Unit 1795